In re International Application of: BIOGEN IDEC INC.

International Application No.: PCT/US03/18253

International Filing Date: 10 June 2003 (10/06/03)

Title: "GENES OVEREXPRESSED BY CANCER AND THEIR USE IN DEVELOPING NOVEL THERAPEUTICS"

International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20
SWITZERLAND

AMENDMENT UNDER PCT ARTICLE 19

Applicant hereby requests amendment of claim 1 as indicated on the attached replacement pages 98, 101, 102, and 103.

Claim 1 is amended to refer to SEQ ID NOs: 40 and 42 in part (b) rather than part (a), as originally filed. The amendment is made on the basis that SEQ ID NOs: 40 and 42 are amino acid sequences encoded by the nucleotide sequences of SEQ ID NOs: 39 and 41, respectively, which are already included in claim 1, part (a). *See* pages 87-89 of the originally filed application.

In addition, the preamble of claim 1 is amended to refer to "[a]n isolated nucleic acid which encodes a cancer cell antigen and which comprises a sequence selected from the group consisting of." As originally drafted, it appears unclear whether the transitory language "consisting of" refers to the group of nucleotide sequences set forth as subpart (a), (b), and (c), or to the isolated nucleic acid. Support for the amendment is found throughout the originally filed application, including, for example, at page 25, lines 5-21, wherein it is stated polynucleotide molecules comprising the disclosed sequences can be used in a polynucleotide construct; at page 3, lines 21-24, wherein it is stated that additional nucleic acids of the invention encode cancer antigens comprising one or more MHC class I binding epitopes and that bind to the complement of the disclosed nucleic acids under high stringent conditions; at page 12, lines 8-14, wherein variant nucleic acids are described based on sequence identity, which includes nucleic acids having extra

COPY

nucleotides; at page 16, lines 10-15, wherein preparation of fusion proteins is described, *i.e.*, by making a DNA construct which comprises a coding sequence encoding an amino acid sequence corresponding to an ovarian antigen of the invention; among other places. These descriptions clearly encompass nucleic acids having variant nucleotide sequences when compared to the sequences specified by SEQ ID NOs., including longer sequences, to support use of "comprising."

Claim 32, which is directed to a treatment method, is amended to properly depend from claim 31. As originally filed, the claim incorrectly depended from claim 29, which is not a method claim.

Claim 40 is amended to replace "reagent" with "therapeutic reagent" as used in claim 36, from which claim 40 depends.

Claim 52 is amended to replace "antibody" with "therapeutic agent" as used in claim 51, from which claim 52 depends.

Entry of the amendments prior to issuance of a Written Opinion is respectfully requested. Given that a demand for international preliminary examination was filed previously, a copy of this amendment is also being transmitted to the International Examination Authority.

Respectfully submitted,
BIOGEN IDEC INC.

Thomas A. Cawley, Jr., Ph.D.
USPTO Registration No. 40,944
Attorney for Applicants

Date: 8 November 2004
TAC/JBM

COPY

WHAT IS CLAIMED IS:

1. An isolated nucleic acid which encodes a cancer cell antigen and which comprises a sequence selected from the group consisting of:

(a) the nucleotide sequence of any one of SEQ ID NOs: 1, 2, 6, 9, 11, 14, 16, 20, 21, 23, 28, 37, 38, 39, 41, 43, and 44;

(b) a nucleotide sequence encoding SEQ ID NO: 22, 32, 40, or 42; and

(c) a nucleotide sequence complementary to (a) or (b).

2. The isolated nucleic acid of claim 1, wherein the cancer cell antigen comprises one or more MHC class I binding epitopes.

3. The isolated nucleic acid of claim 1, wherein the cancer cell antigen has a capability to elicit cytotoxic T cell lysis.

4. An isolated nucleic acid comprising a nucleic acid sequence that is at least 70% identical to the sequence of the nucleic acid of claim 1, and which encodes a cancer cell antigen comprising one or more MHC class I binding epitopes.

5. The isolated nucleic acid of claim 4, wherein the nucleic acid sequence is at least 90% identical to the sequence of the nucleic acid of claim 1.

6. The isolated nucleic acid of claim 4, wherein the cancer cell antigen has a capability to elicit cytotoxic T cell lysis.

7. An isolated nucleic acid encoding a cancer antigen comprising one or more MHC class I binding epitopes, which nucleic acid hybridizes to the complement of the nucleic acid of claim 1 under the following stringent conditions: a final wash in 0.1X SSC at 65°.

8. The isolated nucleic acid of claim 7, wherein the cancer cell antigen has a capability to elicit cytotoxic T cell lysis.

28. The vaccine of claim 27, wherein the one or more MHC-binding epitopes are selected from the group consisting of an HLA-A0201 binding epitope, an HLA-24 binding epitope, an HLA-A3 binding epitope, an HLA-A1 binding epitope, an HLA-B7 binding epitope, and combinations thereof.

29. The vaccine of claim 28, wherein the antigen comprises SEQ ID NO:22, or MHC class I binding fragment thereof.

30. The vaccine of claim 26, further comprising a capability to elicit a humoral or cytotoxic T lymphocyte response to the antigen.

31. A method for treating cancer, which comprises administering to a subject in need thereof a vaccine comprising a therapeutically effective amount of a vaccine of claim 26.

32. The method of claim 31, wherein the vaccine is administered in combination with a chemotherapeutic agent.

33. A monoclonal antibody or antigen binding fragment thereof, which specifically binds to the antigen of claim 21.

34. The monoclonal antibody of claim 33 which is a chimeric, human, or humanized antibody.

35. A diagnostic reagent comprising an antibody or antigen binding fragment of claim 33 and a detectable label.

36. A therapeutic reagent comprising an antibody or antigen binding fragment of claim 33 and an effector moiety bound.

37. The therapeutic reagent of claim 36, wherein the effector moiety is a radionuclide, an enzyme, a cytotoxin, a growth factor, or a drug.

38. A method for treating cancer, which comprises administering to a subject in need thereof a therapeutically effective amount of an antibody or antigen binding fragment of claim 33.

39. The method of claim 38, wherein the antibody is administered in combination with a chemotherapeutic agent.

40. A method for treating cancer, which comprises administering to a subject in need thereof a therapeutically effective amount of a therapeutic reagent of claim 36.

41. The method of claim 40, wherein the therapeutic reagent is administered in combination with a chemotherapeutic agent.

42. A monoclonal antibody or antigen binding fragment thereof that specifically binds Anat-2 antigen.

43. The monoclonal antibody of claim 42 which is a chimeric, human, or humanized antibody.

44. A diagnostic reagent comprising an antibody or antigen binding fragment of claim 42 and a detectable label.

45. A therapeutic reagent comprising the monoclonal antibody or antigen binding fragment of claim 42 and an effector moiety.

46. The therapeutic reagent of claim 45, wherein the effector moiety is a radionuclide, an enzyme, a cytotoxin, a growth factor, or a drug.

47. The therapeutic reagent of claim 46, wherein the radionuclide is ^{90}Y or ^{131}I.

48. The monoclonal antibody or antigen binding fragment of claim 42, which does not specifically bind to Anat-1, Anat-3 or Anat-4.

49. A method of treating cancer comprising administering to a subject in need thereof a therapeutically effective amount of the antibody or antigen binding fragment of claim 42.

50. The method of claim 49, wherein the antibody is administered in combination with a chemotherapeutic agent.

51. A method of treating cancer comprising administering to a subject in need thereof a therapeutically effective amount of the therapeutic reagent of claim 45.

52. The method of claim 51, wherein the therapeutic agent is administered in combination with a chemotherapeutic agent.